

EPA Registration 91384-3
Volume 2



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

Note to File

Date: May 4, 2017

Registration Number: 91384-3

Decision Number: 524329, 523254, 524862

PM/RM Name: Julie Breeden-Alemi/Bo Davis/Gene Benbow

Background: There are three actions in progress for this product.

Decision 524329 is a PRIA action adding CRP Blister Packs and Screw-Top Tube

Decision 523254 is an amendment adding veterinary language

-Included in this amendment is the addition of foil packaging that was denied via notification

Decision 524862 is Storage Stability and Corrosion Characteristics study

Decision: It was decided by management to combine Decision 524329 PRIA amendment and Decision 523254 label amendment into the same review due to the label changes and temporal confluence of the action due dates.

The Storage Stability study was submitted in the same PRIA action as Decision 524329, but separated out into its own Decision.

Decision 523254 was recoded on March 31, 2017 to a non-PRIA amendment (300) as the studies submitted for CRP review were not acceptable as submitted, and thus not fully reviewed. CRP added for this action was the 3-count blister pack, CRP Certification Statement dated March 2, 2017.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

May 9, 2017

Richard L. Conn
CAP IM Supply, Inc.
2825 East Cottonwood Pkwy Ste. 500
Salt Lake City, UT 84121

Subject: Label Amendment –revisions regarding foil pouch, mitigation, and marketing statements; addition of CRP (3-count blister)
Product Name: T2.200 FOR DOGS
EPA Registration Number: 91384-3
Application Date: 28-Oct-2016; 09-Dec-2016
Decision Number: 523254; 524329

Dear Mr. Conn:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2
EPA Reg. No. 91384-3
Decision No. 523254; 524329

with FIFRA section 6. If you have any questions, you may contact Julie Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Gene Benbow".

Gene Benbow, Acting Product Manager 4
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

T2.200 for Dogs
EPA Reg. No. 91384-3

{NOTE TO REVIEWER: Optional text appears in brackets: [] - the final label may include some or all of the optional text on front, back, side, or inside label panels. { } are for notes to reviewer and text location/positioning.}

This product has two alternative Child Resistant Packaging types: 1) applicator without an outer blister pack and 2) blister pack containing an applicator. Cartons have the option of containing a foil pouch. When the foil pouch is included, the CR package, insert, and reminder stickers will be placed inside the pouch.}

{Label Directions and Container (Carton, Overwrap of 2 x 3-Count, 2 x 4-Count, 2 x 6-Count, and 3 x 4-Count Cartons), Package Insert, Individual Applicator, and Reminder Stickers}

ONE CARTON; TWO CARTONS WITH OVERWRAP:

Small dog: 3 x 0.014 FL. OZ. PACKAGE {for 3-count applicator strip with no outer blister; 3-count blister pack containing an applicator}
Medium dog: 3 x 0.034 FL. OZ. PACKAGE {for 3-count applicator strip with no outer blister; 3-count blister pack containing an applicator}
Large dog: 3 x 0.084 FL. OZ. PACKAGE {for 3-count applicator strip with no outer blister; 3-count blister pack containing an applicator}
X-Large dog: 3 x 0.135 FL. OZ. PACKAGE {for 3-count applicator strip with no outer blister; 3-count blister pack containing an applicator}

ONE CARTON; TWO OR THREE CARTONS WITH OVERWRAP:

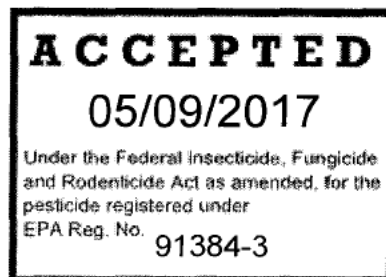
Small dog: 4 x 0.014 FL. OZ. PACKAGE {only for 4-count applicator strip with no outer blister}
Medium dog: 4 x 0.034 FL. OZ. PACKAGE {only for 4-count applicator strip with no outer blister}
Large dog: 4 x 0.084 FL. OZ. PACKAGE {only for 4-count applicator strip with no outer blister}
X-Large dog: 4 x 0.135 FL. OZ. PACKAGE {only for 4-count applicator strip with no outer blister}

ONE CARTON; TWO CARTONS WITH OVERWRAP:

Small dog: 6 x 0.014 FL. OZ. PACKAGE {for two 3-count applicator strips with no outer blister; two 3-count blister packs containing an applicator}
Medium dog: 6 x 0.034 FL. OZ. PACKAGE {for two 3-count applicator strips with no outer blister; two 3-count blister packs containing an applicator}
Large dog: 6 x 0.084 FL. OZ. PACKAGE {for two 3-count applicator strips with no outer blister; two 3-count blister packs containing an applicator}
X-Large dog: 6 x 0.135 FL. OZ. PACKAGE {for two 3-count applicator strips with no outer blister; two 3-count blister packs containing an applicator}

ONE CARTON:

Small dog: 8 x 0.014 FL. OZ. PACKAGE {only for two 4-count applicator strips with no outer blister}
Medium dog: 8 x 0.034 FL. OZ. PACKAGE {only for two 4-count applicator strips with no outer blister}
Large dog: 8 x 0.084 FL. OZ. PACKAGE {only for two 4-count applicator strips with no outer blister}
X-Large dog: 8 x 0.135 FL. OZ. PACKAGE {only for two 4-count applicator strips with no outer blister}



{FRONT PANEL OF OVERWRAP FOR 2 AND 3-CARTON PACKAGES IN CRP DESCRIBED ON PAGE 1:
2 x 3-COUNT, 2 X 4-COUNT, 2 X 6-COUNT, AND 3 X 4-COUNT}

[T2.200 for Dogs]

{Alternate Brand Names are listed at the end of this draft label. The words "for Dogs" is included in each product name and will be at least 75% of the height of the largest letter in the product name. A large clear picture of a dog in the weight range of the product as packaged will be on the front panel.}

Monthly topical treatment and prevention of ticks, fleas, mosquitos, biting flies, and lice.

{The following "FOR USE ONLY" restriction will appear in a box prominently on the front panel of the overwrap, per section III.A.1.b. of the September 30, 2011 EPA letter to registrants}

FOR USE **ONLY** ON DOGS AND PUPPIES 7 WEEKS AND OLDER AND WEIGHING [5-10 LBS.][**SMALL DOGS**] [11-20 LBS.][**MEDIUM DOGS**] [21-55 LBS.][**LARGE DOGS**] [OVER 55 LBS.][**X-LARGE DOGS**]

KEEP OUT OF REACH OF CHILDREN {font size will comply with 40 CFR 156.60(b)}

WARNING {font size will comply with 40 CFR 156.60(b)}

	%
Active Ingredients	<u>By Weight</u>
Imidacloprid	8.80%
Permethrin*	44.00%
Pyriproxyfen	0.44%
Other Ingredients	46.76%
Total	100.00%

*cis/trans ratio: Max 55(±) cis and min 45%(±) trans

See back panel for Precautionary Statements and First Aid information.

See package insert for Directions for Use and Storage and Disposal.

DO NOT USE ON CATS

{A 1.5 CM X 1.5 CM CAT PROHIBITION ICON WILL BE IN A BOX IN THE LOWER RIGHT HAND CORNER OF THE FRONT PANEL IN YELLOW WITH BLACK IMAGE}



Net Contents:

- [2 cartons each containing [3][4][6] applicators, each 0.014 fl. oz. (0.4mL)]
- [2 cartons each containing [3][4][6] applicators, each 0.034 fl. oz. (1.0 mL)]
- [2 cartons each containing [3][4][6] applicators, each 0.084 fl. oz. (2.5 mL)]
- [2 cartons each containing [3][4][6] applicators, each 0.135 fl. oz. (4.0 mL)]
- [3 cartons each containing 4 applicators, each 0.014 fl. oz. (0.4 mL)]
- [3 cartons each containing 4 applicators, each 0.034 fl. oz. (1.0 mL)]
- [3 cartons each containing 4 applicators, each 0.084 fl. oz. (2.5 mL)]
- [3 cartons each containing 4 applicators, each 0.135 fl. oz. (4.0 mL)]

{FRONT PANEL OF CARTON}

[T2.200 for Dogs]

{Alternate Brand Names are listed at the end of this draft label. The words "for Dogs" is included in each product name and will be at least 75% of the height of the largest letter in the product name. A large clear picture of a dog in the weight range of the product as packaged will be on the front panel.}

Monthly topical treatment and prevention of ticks, fleas, mosquitos, biting flies, and lice.

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WARNING {font size will comply with 40 CFR 156.60(b)}

	%
Active Ingredients	<u>By Weight</u>
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See back panel for Precautionary Statements and First Aid information.

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DO NOT USE ON CATS

{A 1.5 CM X 1.5 CM CAT PROHIBITION ICON WILL BE IN A BOX IN THE LOWER RIGHT HAND CORNER OF THE FRONT PANEL IN YELLOW WITH BLACK IMAGES}



Net Contents:

[3][4][6][8] applicators, each 0.014 fl. oz. (0.4 mL)

[3][4][6][8] applicators, each 0.034 fl. oz. (1.0 mL)

[3][4][6][8] applicators, each 0.084 fl. oz. (2.5 mL)

[3][4][6][8] applicators, each 0.135 fl. oz. (4.0 mL)

{BACK PANEL OF CARTON AND OF OVERWRAP FOR 2 AND 3 CARTON PACKAGES IN CRP DESCRIBED ON PAGE 1:
2 X 3-COUNT, 2 X 4-COUNT, 2 X 6-COUNT, AND 3 X 4-COUNT
SEE PAGE 1 FOR CRP OPTIONS}

[T2.200 for Dogs]

{The following overall claim statement can appear either here or immediately after the "READ THE ENTIRE LABEL..." statement.}
Monthly Topical Treatment and Prevention of Ticks, Fleas, Mosquitos, Biting Flies, and Lice [on Dogs].

{The following "FOR USE ONLY" restriction is optional on the back panel of the carton and overwrap}
[FOR USE **ONLY** ON DOGS AND PUPPIES 7 WEEKS AND OLDER AND WEIGHING [5-10 LBS.][**SMALL DOGS**] [11-20 LBS.][**MEDIUM DOGS**] [21-55 LBS.][**LARGE DOGS**] [OVER 55 LBS.][**X-LARGE DOGS**]

READ THE ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on dogs or puppies under seven (7) weeks of age or weighing less than [insert lowest weight of weight class] pounds. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

FIRST AID	
If In Eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-XXX-XXX-XXXX. For consumer questions, call 1-XXX-XXX-XXXX.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

Side Effects:

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy or agitation) occur, consult your veterinarian or call 1-XXX-XXX-XXXX.

{The side effects box will be located immediately above the cat warning box.}

{A 1.5 cm x 1.5 cm cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images.}

DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.



For consumer questions call 1-XXX-XXX-XXXX

For medical emergencies call 1-XXX-XXX-XXXX

CAP IM Supply, Inc.
2825 East Cottonwood Pkwy, Suite 500
Salt Lake City, UT 84121

EPA Est. No. XXXXX-XX-X

EPA Reg No. 91384-3

{SIDE PANELS OF CARTON AND OF OVERWRAP FOR 2 AND 3 CARTON PACKAGES IN CRP DESCRIBED ON PAGE 1:
2 X 3-COUNT, 2 X 4-COUNT, 2 X 6-COUNT, AND 3 X 4-COUNT}

{The following "FOR USE ONLY" restriction is optional on the side panels of the carton and overwrap}

[FOR USE **ONLY** ON DOGS AND PUPPIES 7 WEEKS AND OLDER AND WEIGHING [5-10 LBS.][**SMALL DOGS**] [11-20
LBS.][**MEDIUM DOGS**] [21-55 LBS.][**LARGE DOGS**] [OVER 55 LBS.][**X-LARGE DOGS**]]

[T2.200 for Dogs]

[EPA Reg. No. 91384-3]

Lot/Batch Number

{PACKAGE INSERT LABELING}

{Every carton will contain an insert and when a foil pouch is used, the insert will be inside the foil pouch}

[T2.200 for Dogs]

{Alternate Brand Names are listed at the end of this draft label}

Monthly topical treatment and prevention of ticks, fleas, mosquitos, biting flies, and lice [on dogs].

FOR USE **ONLY** ON DOGS AND PUPPIES 7 WEEKS AND OLDER AND WEIGHING [5-10 LBS.][**SMALL DOGS**] [11-20 LBS.][**MEDIUM DOGS**] [21-55 LBS.][**LARGE DOGS**] [OVER 55 LBS.][**X-LARGE DOGS**]

Active Ingredients	% By Weight
Imidacloprid	8.80%
Permethrin*	44.00%
Pyriproxyfen	0.44%
Other Ingredients	46.76%
Total	100.00%

*cis/trans ratio: Max 55(±) cis and min 45%(±) trans

KEEP OUT OF REACH OF CHILDREN {font size will comply with 40 CFR 156.60(b)}

WARNING {font size will comply with 40 CFR 156.60(b)}

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on dogs or puppies under seven (7) weeks of age or weighing less than [insert lowest weight of weight class] pounds. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

Side Effects:

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy or agitation) occur, consult your veterinarian or call 1-XXX-XXX-XXXX.

FIRST AID	
If In Eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-XXX-XXX-XXXX. For consumer questions, call 1-XXX-XXX-XXXX.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

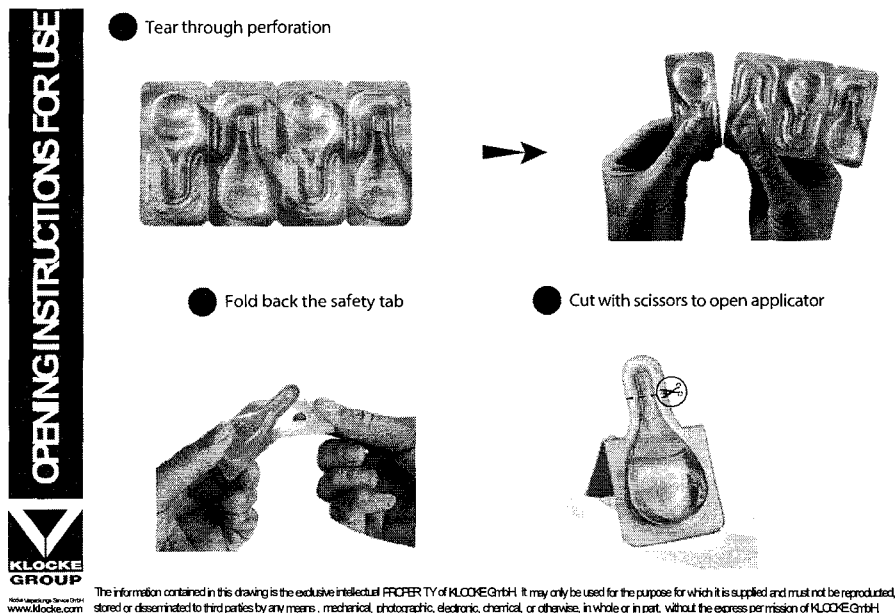
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food. Do not allow children to apply product.

{This product has two alternative Child Resistant Packaging types listed here in the same sequence as illustrated below: 1) applicator without an outer blister pack and 2) blister pack containing an applicator.}

{For CRP: Applicator without a blister}

HOW TO OPEN



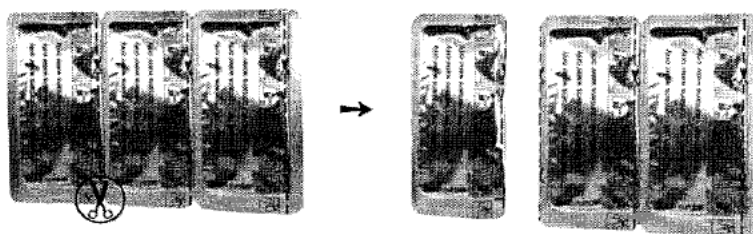
{When this product is packaged as the 3-count or 6-count version, the above image will show a 3-count applicator strip instead of the 4-count as shown above.}

{For CRP: Blister containing applicator}

HOW TO OPEN



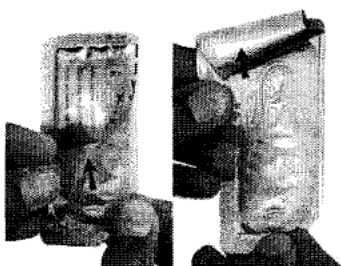
- 1** Cut along scissor cut line to separate unit



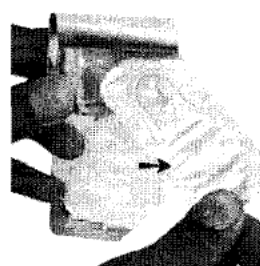
- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



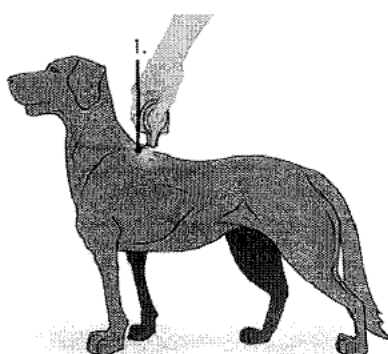
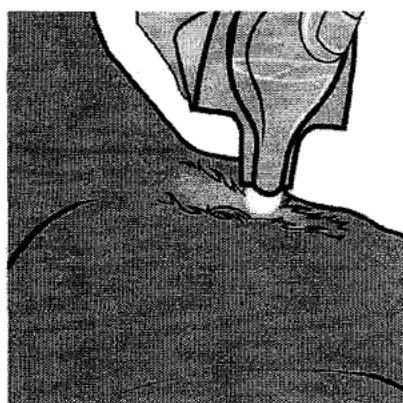
- 4** Remove the applicator



The information contained in this drawing is the exclusive intellectual PROPERTY of KLOCKE GmbH. It may only be used for the purpose for which it is supplied and must not be reproduced, stored or disseminated to third parties by any means, mechanical, photographic, electronic, chemical, or otherwise, in whole or in part, without the express permission of KLOCKE GmbH.

HOW TO APPLY

1. Prepare applicator as shown in "How to Open".
2. {The appropriate text will be used matching the carton weight class and each weight class will have its own separate insert.}
{5 – 10 lbs and 11-20 lbs.}
[Apply the entire contents of the applicator to one spot [as shown]:
{The following visual is optional.}



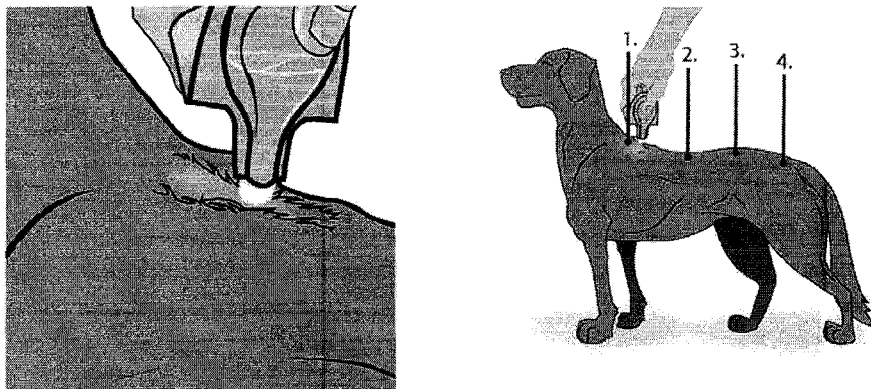
[Part the hair on the dog back between the shoulder blades until the skin is visible. Place the tip of the applicator on the skin and gently squeeze to apply all the contents to the skin.] [Part the dog's hair and

place the tip of the applicator behind the neck and between the shoulders. Squeeze the applicator thoroughly so that the entire contents are applied to one spot.] Carefully avoid allowing the product to run off the side of the dog.

{21 – 55 lbs. and Over 55 lbs.}

Apply the entire contents of the applicator evenly to three or four spots on the top of the back of the dog from the shoulder to the base of the tail [as shown]:

{The following visual is optional.}



At each application site part the hair of the dog until the skin is visible. Place the tip of the applicator on the skin and gently squeeze to apply the solution on the skin. Do not apply an amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

3. Discard empty applicator and packaging as described in the Storage and Disposal section.
4. Under normal conditions the product remains effective for a month. In case of severe pest infestations [at the initiation of treatment], retreatment once a week is permitted not to exceed 4 weeks. [After][With] successful pest control, please return to a monthly schedule.

RESTRICTIONS:

Do not use on cats.

Do not get this product in your dog's eyes.

Do not allow your dog to ingest this product.

Do not apply more than one application per treatment per dog [even for dogs over 55 lbs.]. {Bracketed phrase is mandatory on inserts for dogs over 55 lbs.}

Do not use on dogs under 7 weeks of age or weighing less than the minimum weight shown on the carton and the applicator.

Do not allow adults, children, or pets to touch treated area until dry.

[Keep treated dog off furniture until the treated area is dry.]

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [T2.200 for Dogs] rapidly kills fleas and may reduce the incidence of this condition.

[T2.200 for Dogs] kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting at least four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

[T2.200 for Dogs] is waterproof and remains effective following a shampoo [treatment], swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas and ticks.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. Protect from freezing. **Pesticide Disposal and Container Handling:** Non refillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

{NOTE TO REVIEWER: A warranty statement of any kind is optional, but if a warranty statement is used, the following two alternative options are proposed:}

[LIMITED WARRANTY AND LIMITATION OF DAMAGES

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all of which are beyond the control of CAP IM Supply, Inc. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, CAP IM Supply, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither CAP IM Supply, Inc., the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

[WARRANTY

To the extent consistent with applicable law, CAP IM Supply, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.]

{NOTE TO REVIEWER: The following optional websites, currently under construction, will go live prior to use on any packaging being released for shipment:}

[For more information visit www.pet-lock.com][www.advecta3.com]

DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.



For consumer questions call 1-XXX-XXX-XXXX
For medical emergencies call 1-XXX-XXX-XXXX

EPA Reg No. 91384-3

CAP IM Supply, Inc.
2825 East Cottonwood Pkwy, Suite 500
Salt Lake City, UT 84121

(LABEL TEXT FOR FOIL POUCH)

{The use of a foil pouch is optional.}

Use **Only** on Dogs and Puppies 7 Weeks and older and weighing [5-10 lbs][**SMALL DOGS**] [11-20 lbs][**MEDIUM DOGS**] [21-55 lbs][**LARGE DOGS**] [OVER 55 lbs][**X-LARGE DOGS**]

[T2.200 for Dogs]

ACTIVE INGREDIENTS:	% BY WEIGHT
Imidacloprid	8.80%
Permethrin*	44.00%
Pyriproxyfen	0.44%
OTHER INGREDIENTS	46.76%
TOTAL	100.00%

*cis/trans ratio: Max 55(±) cis and min 45%(±) trans

READ THE ENTIRE LABEL BEFORE USE

KEEP OUT OF REACH OF CHILDREN {font size will comply with 40 CFR 156.60(b)}

WARNING {font size will comply with 40 CFR 156.60(b)}



DO NOT USE ON CATS

EPA Reg. No. 91384-3

CAP IM Supply, Inc.

Net Contents:

[3][4][6][8] applicators each containing 0.014 fl. oz (0.4 mL)
[3][4][6][8] applicators each containing 0.034 fl. oz (1.0 mL)
[3][4][6][8] applicators each containing 0.084 fl. oz (2.5 mL)
[3][4][6][8] applicators each containing 0.135 fl. oz (4.0 mL)

NOT FOR RESALE | [Please] Keep pouch in [carton][box].

{LABEL TEXT FOR INDIVIDUAL APPLICATOR AND BLISTER WHEN USED}

[T2.200 for Dogs]

8.80% imidacloprid
44.00% permethrin
0.44% pyriproxyfen

EPA Reg. No. 91384-3

KEEP OUT OF REACH OF CHILDREN {font size will comply with 40 CFR 156.60(b)}

WARNING {font size will comply with 40 CFR 156.60(b)}

DO NOT USE ON CATS



Read the Entire Label Before Use

[External Use Only] {Will include as room allows on the applicator}

For dogs over 7 weeks of age

CAP IM Supply, Inc

[0.014 fl oz
5-10 LBS.]

[0.034 fl oz
11-20 LBS.]

[0.084 fl oz
21-55 LBS.]

[0.135 fl oz
OVER 55 LBS.]

Lot No. 0000000

{OPTIONAL MARKETING CLAIMS}

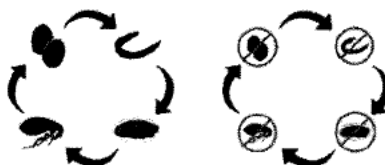
1. For use only on dogs and puppies 7 weeks of age and older and greater than 5 lbs.
2. [T2.200 for Dogs] contains [imidacloprid], [permethrin] and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
3. A single topical application [dose] remains effective for [a month][four](4) weeks]
4. Convenient, easy to apply [monthly] topical solution
5. Once a month topical flea treatment for only dogs 7 weeks of age or older and greater than 5 lbs.
6. [T2.200 for Dogs] is indicated for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice only on dogs [7 weeks of age and older and greater than 5 lbs.]
7. Repels and kills ticks, fleas, and mosquitoes
8. For the treatment and prevention of flea infestations
9. One treatment prevents further flea infestations for [a month][four](4) weeks]
10. Kills fleas on dogs within 12 hours
11. Continues to prevent infestations for [a month][four](4) weeks
12. Kills fleas within 12 hours of application
13. Controls existing flea infestations by rapidly killing adult fleas
14. Prevents reinfestations by killing adult fleas before they lay eggs
15. Effectively breaks the flea life cycle
16. Flea adulticide, larvicide and ovicide
17. Effectively targets all [life] stages of [fleas] and [ticks]
18. 3-way flea protection] [kills] [controls] [adults], [larvae], and] [eggs]
19. Prevents development of fleas, [flea eggs], [pupae] and [larvae] for [a month][four](4) weeks]
20. Prevents development of all flea [life] stages [for] [a month][four](4) weeks]
21. Repels and kills [all] [life] [stages of fleas]
22. Prevents flea eggs [and flea larvae] from developing into [biting] [adult] fleas
23. Treatment with [T2.200 for Dogs] rapidly kills fleas and may reduce the incidence of Flea Allergic Dermatitis (FAD)
24. Repels and kills ticks [including Deer ticks that may transmit Lyme disease]], [American dog ticks that may transmit Rocky Mountain spotted fever]], [Brown dog ticks that may transmit Ehrlichiosis]], and [Lone Star ticks that may transmit Ehrlichiosis]] for up to four weeks
25. Repels and kills mosquitoes [for up to four weeks]
26. Repels and kills mosquitoes often before they have a chance to take a blood meal
27. [Prevents blood-feeding by] [Kills and repels][killing and repelling] mosquitoes
28. Repels and inhibits blood-feeding by biting flies
29. Repels and prevents blood-feeding by biting flies
30. Repels [annoying][bothersome][nuisance] biting flies
31. Inhibits [annoying][bothersome][nuisance] biting flies
32. [Prevents][inhibits] blood-feeding by biting flies
33. Remains effective after bathing [and/or swimming]
34. Remains effective following swimming [and/or shampooing]
35. Kills [biting][chewing] lice
36. For treatment and prevention of [biting][chewing] lice [infestations]
37. Controls existing [biting][chewing] lice infestations
38. 5-way protection against fleas, ticks, biting flies, mosquitoes, and lice
39. Treats, prevents and controls [biting][chewing] lice [infestations]
40. Provides effective control of [biting][chewing] lice [infestations]
41. Kills [biting][chewing] lice and prevents further infestations
42. For treatment and prevention of infestations with [biting][chewing] lice
43. Waterproof
44. Remains effective after exposure to rain or sunlight
45. Fragrance free

46. Contains the same active ingredients imidacloprid, pyriproxyfen and permethrin found in K9 Advantix II.
47. Contains the [same] active ingredients [found] [used] in K9 Advantix II
48. Contains imidacloprid, pyriproxyfen and permethrin, the same active ingredients used in K9 Advantix II
49. Contains the same active ingredients as K9 Advantix II

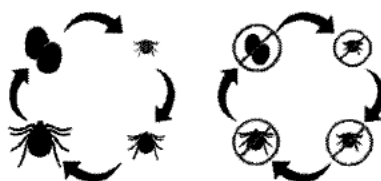
{Whenever any of the four claims immediately above are included on the product label, the label will include the appropriate disclaimers below, which will be placed in the same area of the label as the optional claims so that both are viewed together.}

50. [T2.200 for Dogs] is not manufactured by or distributed by Bayer Health Care LLC
51. K9 Advantix is a registered trademark of Bayer Health Care LLC
52. [T2.200 for Dogs] is not manufactured by or distributed by Bayer Health Care LLC. K9 Advantix is a registered trademark of Bayer HealthCare LLC

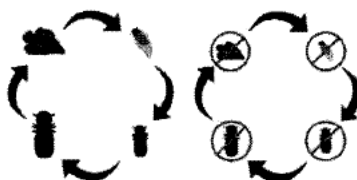
53. 3 Pack [3 Applicators][3 Doses][3 Months' Supply]
54. 4 Pack [4 Applicators][4 Doses][4 Months' Supply]
55. 6 Pack [6 Applicators][6 Doses][6 Months' Supply][6 Months' Total Supply][A Total of 6 Applicators]
56. 8 Pack [8 Applicators][8 Doses][8 Total Doses][8 Months' Supply][8 Months' Total Supply][A Total of 8 Applicators]
57. {this claim may be used on overwrap only}[12 Months' Total Supply][12 Total Doses][A Total of 12 Applicators]
58. [3][4][6][8][12] applicators for the price of [2][3][4][5][6][7][8][9][10][11]
59. Small Dog [5-10 lbs.]
60. Medium Dog [11-20 lbs.]
61. Large Dog [21-55 lbs.]
62. Ex Large Dog [Over 55 lbs.]



63. Illustration of flea life cycle
64. Halts life cycle of fleas



65. Illustration of tick life cycle
66. Halts life cycle of ticks



67. Illustration of [chewing] lice life cycle
68. Halts life cycle of [chewing] lice



69. Illustration of [adult] fleas

70. Kills [and repels] [adult] fleas



71. Illustration of flea eggs

72. Controls hatching of flea eggs



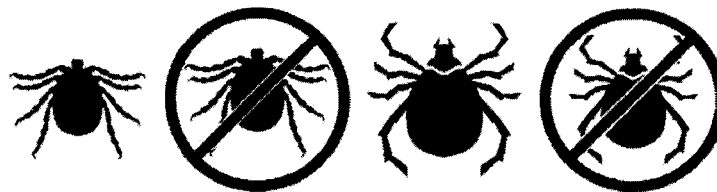
73. Illustration of flea larvae

74. Kills flea larvae



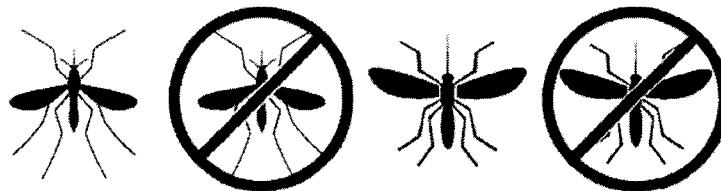
75. Illustration of [chewing] lice

76. Kills [chewing] lice



77. Illustration of tick

78. Kills [and repels] ticks



79. Illustration of mosquito

80. Kills [and repels] mosquitos



81. Illustration of biting fly {biting fly icon will indicate "Biting Fly" to distinguish from other flies}

82. Repels biting flies

83. 5-way protection {Note to reviewer: To be associated with the 5 parasite illustrations.}

84. Picture or illustration of a dog or puppy of appropriate weight class

85. Picture or illustration of the [T2.200 for Dogs] logo

86. Picture or illustration of the primary package, applicator

87. Available from Licensed Veterinarians

88. Available from Licensed Veterinarians {Only use this claim on alternate brand named products sold exclusively to veterinary clinics and shelters}

{TEXT FOR REMINDER STICKERS}
{NOTE TO REVIEWER: This entire section on reminder stickers is optional}

[Optional marketing claims]

Picture of Dog or Puppy 7 weeks or older {dog in picture will be within the weight range of the product as packaged}

Long-lasting

Does not wash off

For monthly control of fleas, ticks, [biting flies], [chewing lice], mosquitoes

Optional Bar Code

[T2.200 for Dogs]

The first time you treat your dog, place the First (Application) Sticker on your calendar. Apply Stickers [2 and 3] [2, 3, 4] [2 through 6] [2 through 8] to the calendar [30 and 60 days] [monthly] [30, 60, and 90 days] [30, 60, 90, 120, and 150 days] [30, 60, 90, 120, 150, 180, and 210 days] [at the end of each 30 day period] after the first [application][dose] to remind you it's time to reapply [T2.200 for Dogs].

First Application [Dose][Sticker]: [Apply] [T2.200 for Dogs]

Month 2 [Sticker]: [Apply] [T2.200 for Dogs]

Month 3 [Sticker]: [Apply] [T2.200 for Dogs]

[Month 4 [Sticker]: [Apply] [T2.200 for Dogs]]

[Month 5 [Sticker]: [Apply] [T2.200 for Dogs]]

[Month 6 [Sticker]: [Apply] [T2.200 for Dogs]]

[Month 7 [Sticker]: [Apply] [T2.200 for Dogs]]

[Month 8 [Sticker]: [Apply] [T2.200 for Dogs]]



Do Not Use on Cats

For Customer Service please call 1-XXX-XXX-XXXX.

CAP IM Supply, Inc.
2825 East Cottonwood Pkwy, Suite 500
Salt Lake City, UT 84121

[Optional bar code]

{ALTERNATE BRAND NAMES}

[ADV Advecta for Dogs]
[ADV Advecta 2 for Dogs]
[ADV Advecta II for Dog]
[ADV Advecta 3 for Dogs]
[ADV Advecta III for Dog]
[ADV PetAction for Dogs]
[ADV PetAction 2 for Dogs]
[ADV PetAction II for Dogs]
[ADV PetAction 3 for Dogs]
[ADV PetAction III for Dogs]
[ADV PetLock for Dogs]
[ADV PetLock 2 for Dogs]
[ADV PetLock II for Dogs]
[ADV PetLock 3 for Dogs]
[ADV PetLock III for Dogs]
[Advecta 3 for Dogs]
[Advecta K9 for Dogs]
[K9 Advecta (Advanced) for Dogs]
[Advecta III for Dogs]
[Advecta ADV for Dogs]
[Advecta ADV 2 for Dogs]
[Advecta ADV II for Dogs]
[Advecta ADV 3 for Dogs]
[Advecta ADV III for Dogs]
[Advecta Complete for Dogs]
[Advecta Max for Dogs]
[Advecta Ticks for Dogs]
[Advecta Tix for Dogs]
[K9 Advecta Tix for Dogs]
[Advecta Tix K9 for Dogs]
[Canine Advecta Tix for Dogs]
[Advecta Tix Canine for Dogs]
[Advecta Total for Dogs]
[K9 Advecta Total for Dogs]
[Canine Advecta Total for Dogs]
[Advecta Total K9 for Dogs]
[Advecta Total Canine for Dogs]
[Advectix for Dogs]
[Advectix K9 for Dogs]
[K9 Advectix for Dogs]
[Advectix Canine for Dogs]
[Canine Advectix for Dogs]
[Advectix 2 for Dogs]
[K9 Advectix 2 for Dogs]
[Advectix K9 for Dogs]
[Canine Advectix 2 for Dogs]
[Advectix Canine 2 for Dogs]
[Advectix II for Dogs]
[K9 Advectix II for Dogs]
[Advectix II K9 for Dogs]
[Canine Advectix II for Dogs]
[Advectix II Canine for Dogs]
[Advectix 3 for Dogs]
[K9 Advectix 3 for Dogs]
[Advectix 3 K9 for Dogs]

[Canine Advectix 3 for Dogs]
 [Advectix 3 Canine for Dogs]
 [Advectix III for Dogs]
 [K9 Advectix III for Dogs]
 [Advectix III K9 for Dogs]
 [Canine Advectix III for Dogs]
 [Advectix III Canine for Dogs]
 [Para| Defense 3 for Dogs]
 [K9 Para| Defense 3 for Dogs]
 [Canine Para| Defense 3 for Dogs]
 [Para| Defense K9 3 for Dogs]
 [Para| Defense Canine 3 for Dogs]
 [Para| Defense Advanced for Dogs]
 [K9 Para| Defense Advanced for Dogs]
 [Canine Para| Defense Advanced for Dogs]
 [Para| Defense K9 Advanced for Dogs]
 [Para| Defense Canine Advanced for Dogs]
 [Para| Defense Complete for Dogs]
 [K9 Para| Defense Complete for Dogs]
 [Canine Para| Defense Complete for Dogs]
 [Para| Defense K9 Complete for Dogs]
 [Para| Defense Canine Complete for Dogs]
 [Para| Defense Extra for Dogs]
 [K9 Para| Defense Extra for Dogs]
 [Canine Para| Defense Extra for Dogs]
 [Para| Defense Extra K9 for Dogs]
 [Para| Defense Extra Canine for Dogs]
 [Para| Defense Flea & Tick for Dogs]
 [K9 Para| Defense Flea & Tick for Dogs]
 [Canine Para| Defense Flea & Tick for Dogs]
 [Para| Defense Flea & Tick K9 for Dogs]
 [Para| Defense Flea & Tick Canine for Dogs]
 [Para| Defense III for Dogs]
 [K9 Para| Defense III for Dogs]
 [Canine Para| Defense III for Dogs]
 [Para| Defense III K9 for Dogs]
 [Para| Defense Canine III for Dogs]
 [Para| Defense Max for Dogs]
 [K9 Para| Defense Max for Dogs]
 [Canine Para| Defense Max for Dogs]
 [Para| Defense Max K9 for Dogs]
 [Para| Defense Canine Max for Dogs]
 [Para| Defense Plus Tick Control for Dogs]
 [K9 Para| Defense Plus Tick Control for Dogs]
 [Para| Defense Pro for Dogs]
 [K9 Para| Defense Pro for Dogs]
 [Canine Para| Defense Pro for Dogs]
 [Para| Defense Pro K9 for Dogs]
 [Para| Defense Canine Pro for Dogs]
 [Para| Defense Multi-Vector for Dogs]
 [K9 Para| Defense Multi-Vector for Dogs]
 [Canine Para| Defense Multi-Vector for Dogs]
 [Para| Defense Multi-Vector K9 for Dogs]
 [Para| Defense Canine Multi-Vector for Dogs]
 [Para| Defense Plus Ticks for Dogs]
 [K9 Para| Defense Plus for Dogs]
 [Canine Para| Defense Plus for Dogs]

[Para | Defense Plus K9 for Dogs]
 [Para | Defense Plus Canine for Dogs]
 [Para | Defense Tix for Dogs]
 [K9 Para | Defense Tix for Dogs]
 [Canine Para | Defense Tix for Dogs]
 [Para | Defense Tix K9 for Dogs]
 [Para | Defense Canine Tix for Dogs]
 [PetAction 3 for Dogs]
 [PetAction 3 K9 for Dogs]
 [PetAction 3 Canine for Dogs]
 [K9 PetAction 3 for Dogs]
 [Canine PetAction 3 for Dogs]
 [PetAction III for Dogs]
 [PetAction III K9 for Dogs]
 [PetAction III Canine for Dogs]
 [K9 PetAction III for Dogs]
 [Canine PetAction III for Dogs]
 [PetAction K9 (Advanced) for Dogs]
 [K9 PetAction (Advanced) for Dogs]
 [PetAction ADV for Dogs]
 [PetAction ADV K9 for Dogs]
 [PetAction ADV Canine for Dogs]
 [K9 PetAction ADV for Dogs]
 [Canine PetAction ADV for Dogs]
 [PetAction ADV 2 for Dogs]
 [K9 PetAction ADV for Dogs]
 [Canine PetAction ADV for Dogs]
 [PetAction ADV II for Dogs]
 [K9 PetAction ADV II for Dogs]
 [Canine PetAction ADV II for Dogs]
 [PetAction ADV 3 for Dogs]
 [K9 PetAction ADV 3 for Dogs]
 [Canine PetAction ADV 3 for Dogs]
 [PetAction ADV III for Dogs]
 [K9 PetAction ADV III for Dogs]
 [Canine PetAction ADV III for Dogs]
 [PetAction Complete for Dogs]
 [K9 PetAction Complete for Dogs]
 [Canine PetAction Complete for Dogs]
 [PetAction Max for Dogs]
 [K9 PetAction Max for Dogs]
 [Canine PetAction Max for Dogs]
 [PetAction Ticks for Dogs]
 [K9 PetAction Ticks for Dogs]
 [Canine PetAction Ticks for Dogs]
 [PetAction Tix for Dogs for Dogs]
 [K9 PetAction Tix for Dogs]
 [Canine PetAction Tix for Dogs]
 [PetAction Total for Dogs]
 [K9 PetAction Total for Dogs]
 [Canine PetAction Total for Dogs]
 [PetLock 3 for Dogs]
 [K9 PetLock 3 for Dogs]
 [Canine PetLock 3 for Dogs]
 [PetLock 3 K9 for Dogs]
 [PetLock 3 Canine for Dogs]
 [PetLock K9 for Dogs]

[K9 PetLock for Dogs]
[PetLock III for Dogs]
[K9 PetLock III for Dogs]
[Canine PetLock III for Dogs]
[PetLock III K9 for Dogs]
[PetLock III Canine for Dogs]
[PetLock ADV for Dogs]
[K9 PetLock DV for Dogs]
[Canine PetLock ADV for Dogs]
[PetLock ADV K9 for Dogs]
[PetLock ADV Canine for Dogs]
[PetLock ADV 2 for Dogs]
[K9 PetLock ADV 2 for Dogs]
[PetLock ADV 2 Canine for Dogs]
[PetLock ADV II for Dogs]
[K9 PetLock ADV II for Dogs]
[PetLock ADV II Canine for Dogs]
[PetLock ADV 3 for Dogs]
[K9 PetLock ADV 3 for Dogs]
[PetLock ADV III for Dogs]
[K9 PetLock ADV III for Dogs]
[PetLock ADV III Canine for Dogs]
[PetLock Complete for Dogs]
[PetLock Max for Dogs]
[PetLock Ticks for Dogs]
[K9 PetLock Ticks for Dogs]
[Canine PetLock Ticks for Dogs]
[PetLock Tix for Dogs]
[PetLock tix K9 for Dogs]
[PetLock Tix Canine for Dogs]
[PetLock Total for Dogs]
[K9 PetLock Total for Dogs]
[Canine PetLock Total for Dogs]
[PetLock Total K9 for Dogs]
[PetLock Total Canine for Dogs]
[K9 Lock II for Dogs]
[Provecta Advanced for Dogs]

Breeden-Alemi, Julie

From: Richard L. Conn <richard@connsmith.com>
Sent: Monday, May 08, 2017 11:31 AM
To: Breeden-Alemi, Julie
Cc: John Tatum; 'Katie Brenner'
Subject: Re: Reg. No. 91384-3
Attachments: T2 200 for Dogs amendments proposed label May 8 2017 track changes.pdf; 091384-00003.20170508.T2.200 for Dogs.pdf

Good morning Julie,
CAP IM Supply, Inc. is in full agreement with your comment this morning to have 4 separate inserts, and the label has been revised exactly as you requested. Both the track changes version (compared to the May 5, 2017 version) and the clean version are attached as PDF files. We're looking forward to the next step!
Best regards,
Richard

On 5/8/2017 7:44 AM, Breeden-Alemi, Julie wrote:

Good morning Richard,

I hope you had a nice weekend. Thank you for sending the materials last week. I am ready to move this forward, but for one clarification.

I have one question regarding your bullet #1 below. There needs to be a separate insert for each weight range. I'm not sure if you are saying that the same text/illustrations are pertinent for both the 21-55 lb range and the >55 lb range, and that each will have its own insert, but the language is the same (but for the one restriction) OR if you are saying that you plan to combine the 21-55 lb range and >55 lb range on the same insert (which wouldn't work) such that the exact same insert would be found in both of these product packages rather than being specific for each. Similarly there should be a separate insert for 5-10 lb range and the 11-20 lb range. It seems like this might be the last clarification that we need.

See the attached single label comment related to this topic.

If further discussion is needed, let me know.

Thank you,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1

From: Richard L. Conn [<mailto:richard@connsmith.com>]
Sent: Friday, May 05, 2017 2:40 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: John Tatum <John.Tatum@CAPSupplyInc.com>; 'Katie Brenner' <katie.brenner@petiq.com>
Subject: Re: Reg. No. 91384-3

Hi Julie,
Attached are the items you requested:

1. Clean version of the label revised as you requested, dated May 5, 2017. To answer the question you asked on page 11, CAP IM Supply, Inc. does not anticipate using the bracketed phrase "even for dogs over 55 lbs." on package inserts other than those that include dogs over 55 lbs., however CAP IM Supply, Inc. does intend to print one insert that will jointly cover both 21-55 lbs. and over 55 lbs. dogs since the dog graphics in the How to Apply section of the insert are identical for both of those dog sizes. Please note that today we have added one new optional (bracketed) statement as the last point in the list of Restrictions on page 11 which says "[Keep treated dog off furniture until the treated area is dry.]" That new optional restriction is based on some recent real world experience and CAP IM Supply, Inc. decided that it may (optionally) want to use this statement in the insert.
2. Marked label from which the May 5, 2017 clean version was created, showing all changes as compared to the March 31, 2017 version you had seen earlier.
3. EPA Form 8570-34 "Certification with Respect to Citation of Data" that now bears the date of May 5, 2017.
4. EPA Form 8570-35 Agency Internal Use Copy, dated May 5, 2017, modified to delete citations not relevant to this version of T2.200 for Dogs. We deleted the storage stability citation you mentioned in your email yesterday because that citation only pertained to the screw top tube package that is not included for T2.200 for Dogs at this time. We also deleted the last two citations for child resistant packaging because they both pertained to 2-count blister packs that are not included for T2.200 for Dogs at this time.
5. EPA Form 8570-35 Public File Copy, dated May 5, 2017, which matches the Agency version discussed above.

I believe this allows us to reach the end of the processing of this fast track amendment submission package, but please let me know if you see anything that needs further revision.

Best regards,
Richard

On 5/4/2017 4:32 PM, Breeden-Alemi, Julie wrote:

Hi Richard!

Thank you for the labels... we are just about finished! There are just a few tweaks. Good news... I received confirmation that it is ok for you to use exhaust the 50,000 foil labels as requested.

In addition to the few tweaks in the attached label comments we need a revised data matrix removing the two recently added CRP MRIDs that weren't formally reviewed in this action and don't pertain to the CRP currently approved and on the label. I believe it is the last two entries on the matrix dated 12/9/16. Also please change the notation "submitted today" to "submitted" under Storage and Stability. That review is still pending. Since the date will be modified on that matrix, we'll also need a revised Certification with Respect to Citation of Data form that updates the new date on the data matrix.

If you have questions about the remaining comments, feel free to give me a call. I'm not usually in the office on Fridays, but this week I am. This should be it!

Thanks so much and have a great afternoon,
Julie

Julie A. Breeden-Alemi, DVM

U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1

From: Richard L. Conn [<mailto:richard@connsmith.com>]
Sent: Wednesday, May 03, 2017 3:29 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Benbow, Gene <Benbow.Gene@epa.gov>; John Tatum <John.Tatum@CAPSupplyInc.com>; 'Katie Brenner' <katie.brenner@petiq.com>
Subject: Re: Reg. No. 91384-3

Hi Julie,

Attached are the fully revised labels, both clean and marked, as requested. We adopted all of the revisions you specified. This label started with the clean version of the most recent (March 31) version on which you had commented, so the marked changes are what differs from the March 31 version.

CAP IM Supply, Inc. is hereby making one small request that will allow it to exhaust a small supply of already printed foil pouches when they produce product the first time with this latest version of the label, which we anticipate EPA will stamp accepted in the near future. That one small request is to allow CAP IM Supply, Inc. to use those already printed foil pouches bearing "NOT FOR RETAIL SALE" instead of the phrase shown on the attached label which is "NOT FOR RESALE" until that current small supply of foil pouches is exhausted. Those already printed foil pouches match exactly with the labeling for the foil pouch that is shown on page 14 of 23 in the attached clean file except for the NOT FOR RETAIL SALE statement. John Tatum has estimated the small supply of foil pouches to number about 50,000.

If you need any further tweaks to the label prior to acceptance, please let me know and we will very quickly make any such changes.

Best regards,
Richard

On 4/27/2017 4:44 PM, Breeden-Alemi, Julie wrote:

Hi Richard,

Attached are label comments for Reg. No. 91384-3.

There is ongoing internal discussion regarding the "sample" language. At this time only "samples" of 1 and 2 applicators have been approved, and there is concern in expanding that notation to include a larger number of applicators at this time. Therefore, you will see that I have marked through related notations on the label.

I am out of the office tomorrow, but I will be back on Monday. Please use the clean version of this label to indicate any further mark-ups/changes.

I'll look forward to the revised labels (clean and marked), and hope we can finish this action up for you in the very near future in preparation for your upcoming CRP submission.

Have a wonderful weekend!

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSP / OPP / RD / IVB1

From: Richard L. Conn [<mailto:richard@connsmith.com>]
Sent: Wednesday, April 19, 2017 4:30 PM
To: Benbow, Gene <Benbow.Gene@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>; John Tatum <John.Tatum@CAPSupplyInc.com>
Subject: Re: follow-up to phone call last week

Hi Gene,
CAP IM Supply submitted MRIDs 49788710 (carpet study) and 49788711 (home environment study). The citations of those studies:

49788710 Neethling, W. (2015) A Study to Assess the Efficacy of T2 Formulati
on to Control Fleas (Ctenocephalides felis) in a Dog's Environment
Through Assessing Flea Egg Development In Vitro on Carpet Samples F
inal Report. Project Number: CV/15/152, PN1767. Unpublished study
prepared by ClinVet International (Pty) Ltd. 99p.

Trade Secret Status: Document Contains CBI

Submitter: CAP IM SUPPLY, INC.
Submitter No. Submission Date Accession No.
091384 12/07/15 497887 10

Administrative No: 091384-3

NO laboratory records for MRID: 49788710

*** Chemistry Indexing ***
SUBSTANCE CLASS: Single FORMULATION:
Not Formulated Pesticide
Permethrin, mixed cis,trans (109701)

SUBSTANCE CLASS: Single FORMULATION:
Not Formulated Pesticide
Pyriproxyfen (129032)

SUBSTANCE CLASS: Single FORMULATION:
Not Formulated Pesticide
Imidacloprid (129099)

*** Subject Indexing ***
ROOT DT: 1005
Pesticide Use - Product Performance
(Efficacy)
GUIDELINE: 810.3300
Treatments to Control Pests of Humans and
Pets
CONTENT CATEGORY: Complete Primary Report --
Experimental Research

DT SITE: CARPETS (HOSPITAL, COMMERCIAL,
HOUSEHOLD)

DT PEST: FLEAS

*** Key Author Information ***

DOCUMENT TYPE: Unpublished Monograph

AUTHOR: NULL

TITLE: A Study to Assess th

DATE: 11/17/15

NO related Documents for MRID: 49788710

49788711 Neethling, W. (2015) A Randomised, Negative
Controlled Study Assess
ing the Efficacy of Formulation T2 in the Prevention of
Flea (Cteno
cephalides felis) Infestations on Dogs in a Simulated
Home Environm
ent Final Report. Project Number: CV/15/153,
PN1767. Study prepar
ed by ClinVet International (Pty)
Ltd. 114p.

Trade Secret Status: Document Contains CBI

Submitter: CAP IM SUPPLY, INC.

Submitter No. Submission Date Accession No.

091384 12/07/15 497887 11

Administrative No: 091384-3

NO laboratory records for MRID: 49788711

*** Chemistry Indexing ***

SUBSTANCE CLASS: Single FORMULATION:
Not Formulated Pesticide
Permethrin, mixed cis,trans (109701)

SUBSTANCE CLASS: Single FORMULATION:
Not Formulated Pesticide
Pyriproxyfen (129032)

SUBSTANCE CLASS: Single FORMULATION:
Not Formulated Pesticide
Imidacloprid (129099)

*** Subject Indexing ***

ROOT DT: 1005

Pesticide Use - Product Performance
(Efficacy)

GUIDELINE: 810.3300

Treatments to Control Pests of Humans and
Pets

CONTENT CATEGORY: Complete Primary Report --
Experimental Research

DT SITE: DOGS (ALL OR
UNSPECIFIED)

DT PEST: FLEAS

*** Key Author Information ***

DOCUMENT TYPE: Unpublished Monograph

AUTHOR: NULL
TITLE: A Randomised, Negati
DATE: 10/22/15

NO related Documents for MRID: 49788711

The efficacy review (DP barcode: 431031) dated July 27, 2016, found both studies unacceptable, so we had to remove these MRIDs from our data matrix. We ended up choosing to use the cite-all method of support for efficacy requirements due to the findings in the July 27, 2016 efficacy review on these and the other MRIDs CAP IM Supply had submitted to support T2.200 for Dogs.

John Tatum and I discussed this today and our wish is that we go with whatever wording for claims regarding the dog's environment that the Agency thinks is supportable and consistent with similar claims for products similar to T2.200 for Dogs (containing permethrin, pyriproxyfen, and imidacloprid). We would prefer that this issue regarding claims in the dog's environment not cause delay in completing the review of the T2.200 for Dogs amendments in the current fast track amendment application. In my review of this topic today, I noted that the January 13, 2017 stamped labels for the comparable Bayer products (Advantix II) no longer have the claims regarding the dog's surroundings or the dog's environment that had been on those labels since they were first registered in 2007, and I now anticipate that you will request that T2.200 for Dogs become consistent with that precedent.

Best regards,
Richard

On 4/19/2017 9:09 AM, Benbow, Gene wrote:

Hi Richard,

We've been having further discussions related to environment claims for spot-ons (among other things), and I recalled that you guys had mentioned that you had 'carpet' data to support such a claim. Can you provide/point out the MRID(s) on your data matrix that you are referring to which you feel supports this type of claim? Julie is in possession of all of your application materials, so I've copied her on this email –

Thanks,

Gene Benbow
Acting Product Manager 4
Invertebrate & Vertebrate Branch 1
Registration Division
703-347-0235

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Richard L. Conn, President, Conn & Smith, Inc.

6713 Catskill Rd, Lorton VA 22079-1113, USA
Phone: (703) 339-4199
<http://www.connsmith.com>